PO#2B1123　TMB-1018-A　英文说明书（A0）

印色：单黑

材质：80g书写纸

尺寸：100*142 mm

CE 0123

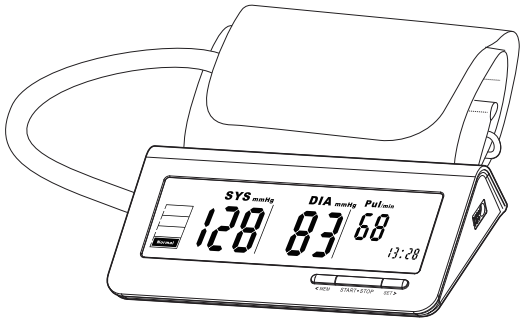
Version:1.0

TRANSTEK

User Manual

Blood Pressure Monitor　TMB-1018-A

Arm Type



- Thank you very much for selecting TRANSTEK Blood Pressure Monitor TMB-1018-A.
- To use the monitor correctly and safely, please read the manual thoroughly.
- Please keep this manual well in order to reference in future.

CE 0123

Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105 ,Dongli Road, Torch Development District,
Zhongshan,528437,Guangdong,China
EC REP MDSS - Medical Device Safety Service GmbH
Schiffgraben 41, 30175 Hannover, Germany

CATALOGUE

Table of Contents

♥ General Description

Thank you for selecting TRANSTEK arm type blood pressure Monitor (TMB-1018-A). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- 140*36mm Digital LCD display
- Maximum 60 records per user
- Measuring during inflation technology

♥ Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
CE 0123	Symbol for “COMPLIES WITH MDD 93/42/EEC REQUIREMENTS”		Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “MANUFACTURER”		
SN	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”	EC REP	Symbol for “Authorised Representative in the European Community
	Symbol for “MANUFACTURE DATE”		Caution: These notes must be observed to prevent any damage to the device

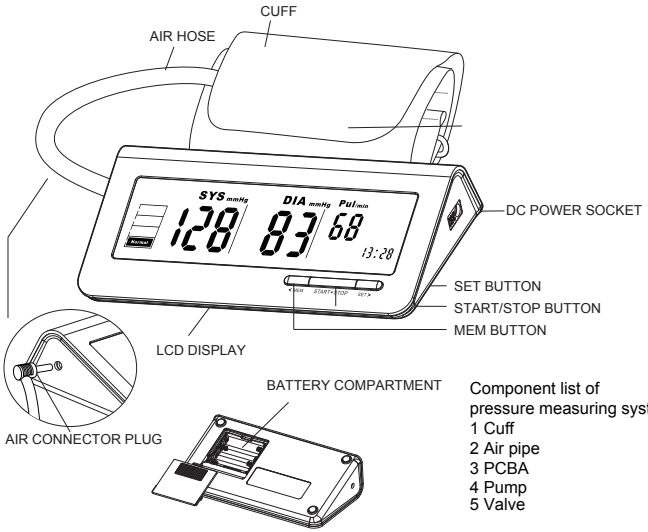
⚠ CAUTION

This device is intended for adult use only.
This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure.Do not begin or end medical treatment without asking a physician for treatment advice.
If you are taking medication,consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your Physician.
When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
If the cuff pressure exceeds 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
The operator shall not touch output of batteries /adapter and the patient simultaneously.
To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
The user must check that the equipment functions safely and see that it is in proper working condition before being used.
This device is contraindicated for any female who may be suspected of, or is pregnant.
Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
Manufacturer will make available on request circuit diagrams, component parts list etc.
This unit is not suitable for continuous monitoring during medical emergencies or operations.
Otherwise, the patient’s arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensization or irritation reaction.
Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
The device doesn’t need to be calibrated within the two years of reliable service.
Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Transtek. Don’t open or repair the device by yourself.
Please report to Transtek if any unexpected operation or events occur.
Please use the soft cloth to clean the whole unit. Don’t use any abrasive or volatile cleaners.

♥ LCD Display Signal

SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pul/min	Pulse per minute	Beats per minute, BPM
▼	Deflating	CUFF air is exhausting of deflating
AM 8:59	Time (hour:minute)	Currently time
M 18/68	Memory	If “M” shows, the displayed measurement values are from the memory.
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
Lo	Low battery	Batteries are low and need to be replaced
	Shocking reminding	Shocking will result in inaccurate
AVG	Average	The average of blood pressure
	Recalling	The records will be showed
	Arrhythmia	Irregular heartbeat
Normal	Grade	The grade of the blood pressure.
M D 88/88	Date	“M” shows the month, “D” shows the day

♥ Monitor Components



Component list of pressure measuring system
1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve

♥ List

1.Blood Pressure Monitor (TMB-1018-A)

2.Cuff Type BF applied part

3. 4*AAA batteries

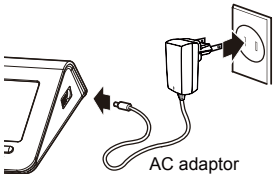
4.User manual

♥ The Choice of Power Supply

1.Battery powered mode:
6VDC 4*AAA batteries

2.AC adaptor powered mode:
6V ⎓ 1A
(Please only use the recommended AC adaptor model) (Not Included).

Please unplug the adaptor to depart from the using utility power.

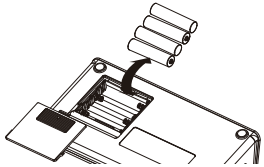


⚠ CAUTION

In order to get the best effect and protect your monitor,please use the right battery and special power adapter which complies with CE safety standard.

♥ Installing and Replacing the Batteries

- . Slide off the battery cover.
- . Install the batteries by matching the correct polarity, as shown.
- . Replace the cover.



Replace the batteries whenever the below happen

- The  shows
- The display dims
- The display does not light up

⚠ CAUTION

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, do not dispose with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

♥ Setting Date, Time and Measurement Unit

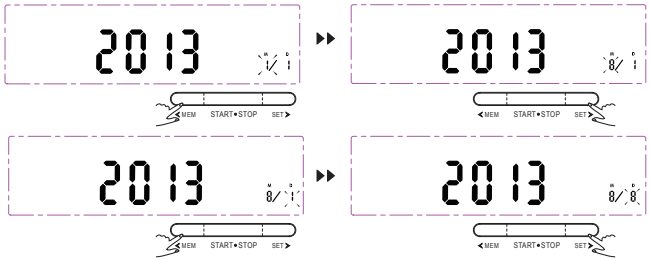
It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year :2000—2050, time:24 H)

1.When the monitor is off, hold pressing “SET” for 3 seconds to enter the mode for year setting.

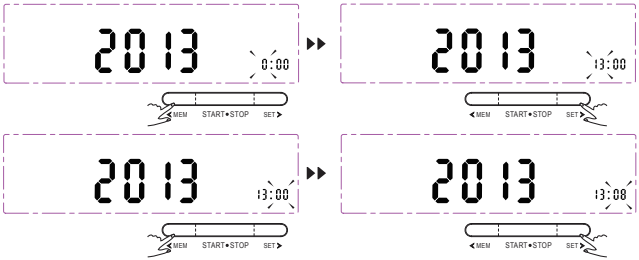
2.The [YEAR] blinks, press the “MEM” button to change the numeral of the year.

3.When you get the right year, press “SET” to set down and turn to next step.

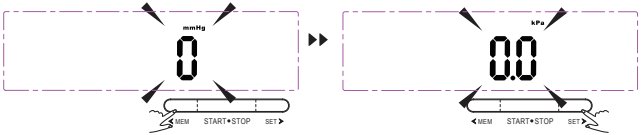
4.Repeat steps 2 and 3 to set the [MONTH] and [DAY].



5.Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



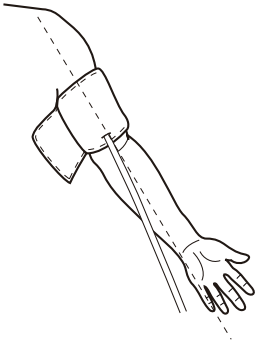
6.Repeat steps 2 and 3 to set the [UNIT].



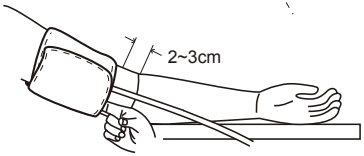
7.After the unit is set,the right picture will show,then it turn off .

♥ Tie the Cuff

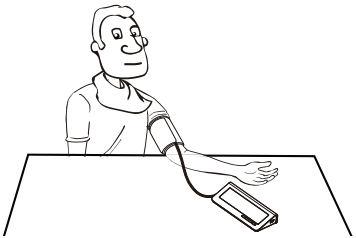
1.Tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger.



2.The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



3.Sit comfortably with your tested arm resting on a flat surface.



• Rest for 5 minutes before measuring.
• Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
• For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

♥ Start the Measurement

1.When the monitor is off,press the "START/STOP" to turn on the monitor, and it will finish the whole measurement.

LCD display

Adjust the zero.

Inflating and measuring.

Display and save the results.

2.Press the "START/STOP" to power off, otherwise it will turn off within 1 minute.

♥ Recall the Records

1. When the monitor is off, press the "MEM" to show the average of the last three measurement records.

The sign of "AVG" will show in the right corner.

2. Press the "MEM" or "SET" to get the record you want.

UP DOWN

The order of the record,date, time will display alternately.

The Order Number of the measurement: 1. Total three records.

The corresponding date is August 8th.

The corresponding time is 13:28.

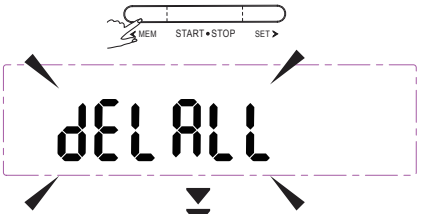
⚠ CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

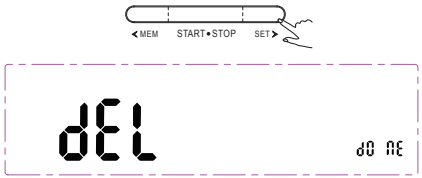
♥ Delete the Records

If you did not get the correct measurement, you can delete all results by following steps below.

1.When the monitor is off, hold pressing “MEM” for 3 seconds ,the flash display will show.

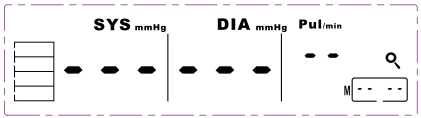


2.Press “SET” to confirm deleting and the monitor will turn off .



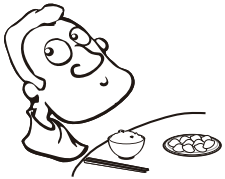
3.If you don’t want to delete the records, press “START/STOP” to escape.

4. If there is no record. the right display will show.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



Immediate measurement after dinner or drinking

Immediate measurement after tea, coffee, smoking

Immediate measurement after taking a bath

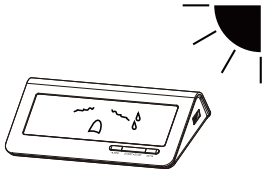
When talking or moving your fingers

In a very cold environment

When you want to discharge urine

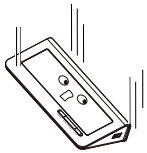
♥ Maintenance

In order to get the best performance, please follow the instructions below.



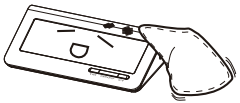
Put in a dry place and avoid the sunshine

Avoid touching water, clean it with a dry cloth in case.

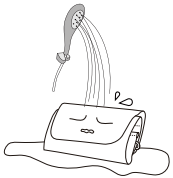


Avoid intense shaking and collisions

Avoid dusty and unstable temperature environment



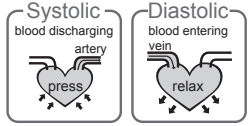
Using wet cloths to remove dirt



Avoid washing the cuff

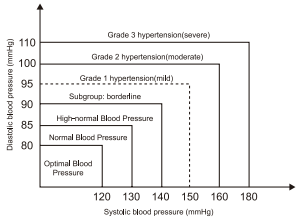
♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥ What is the standard blood pressure classification?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



⚠ CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Level / Blood Pressure (mm Hg)	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180
DIA	<80	80-84	85-89	90-99	100-109	≥110

♥ Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure.During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15,the irregular heartbeat symbol appears on the symbol when the measurement results are displayed.

⚠ CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heart-beat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2.If the person takes medicine, the pressure will vary more.

3.Wait at least 3 minutes for another measurement.

♥ Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc, Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home:

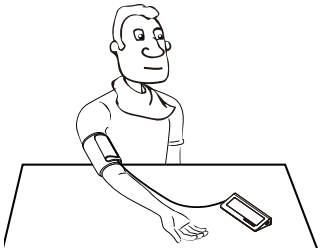
If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.

Taking 2-3 deep breaths before beginning will be better for measuring.

Advice: Relax yourself for 4-5 minutes until you calm down.

♥ Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm every time.



This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

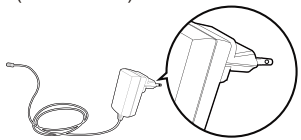
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or show Lo	Batteries are low.	Replace with new batteries
Error massage	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is very tight	Readjust the cuff ,not too loose or too tight and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E10 or E11 shows	The monitor detected motion,talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.

Power supply	Battery powered mode: 6VDC 4*AAA batteries AC adaptor powered mode: 6V ⎓ 1A (Please only use the recommended AC adaptor model) (Not Included).
Display mode	Digital LCD V.A.140mm*36mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0kPa - 40kPa (0mmHg~300mmHg) Measurement pressure: 5.3kPa-30.7kPa (40mmHg-230mmHg) pulse value: (40-199) beat/minute
Accuracy	Pressure: 5℃-40℃within±0.4kPa(3mmHg) pulse value:±5%
Normal working condition	Temperature:5℃ to 40℃ Relative humidity ≤85%RH Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20℃-60℃ Relative Humidity: 10%RH-93%RH Atmospheric Pressure: 50kPa-106 kPa
Measurement perimeter of the upper arm	About 22cm~32cm
Net Weight	Approx.270g(Excluding the dry cells)
External dimensions	Approx.180mm*100mm*40mm
Attachment	4*AAA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Software Version	V01

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. Please use the TRANSTEK authorized adapter (Not Included).



Adapter
Type: UE08WCP-060100SPA
Input: 100~240V, 50~60Hz,400mA
Output: 6V ⎓ 1A
(Conforms to UL certificate)

♥ Contact Information

For more information about our products, please visit www.transtek.cn.you can get customer service, usual problems and customer download, transtek will serve you anytime.

Manufactured by: Guangdong Transtek Medical Electronics Co., Ltd.
Company: Guangdong Transtek Medical Electronics Co., Ltd.
Address: Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China

Authorized European Representative:
Company: MDSS - Medical Device Safety Service GmbH
Address: Schiffgraben 41, 30175 Hannover, Germany

♥ Complied European Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	EN 60601-1: 2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11: 2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements	EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ EMC Guidance

Table 1 Guidance and MANUFACTURER's declaration – ELECTROMAGNETIC EMISSIONS- for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4 Guidance and MANUFACTURER's declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 6 Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmittters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.690	3.690	7.378
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance ***d*** in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			